REMARKS

Claims 1-29, 31-35, 41-42 and 44-50 are pending, claims 30, 36-40 and 43 have been cancelled, and claims 23, 26, 29, 31, 33, 35, 41, 42 and 44 are withdrawn. Applicants have cancelled claims 30, 36-40 and 43 without prejudice. Applicants expressly reserve the right to pursue the cancelled subject matter in this application or subsequent applications that claim the benefit of this application.

Applicants have amended claims 7, 16, 17, 18, 24, 25 and 28 to improve their form and to more particularly point out what applicants intend to pursue in this application. The amended claims are fully supported by the specification (e.g., Examples 2 and 3) and originally filed claims 7, 16, 17, 18, 24, 25 and 28. Additional support for amended claim 24 is found at page 17, lines 13-14. Accordingly, no new matter has been introduced.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

DETAILED ACTION

Election/Restriction

1-2. Applicants acknowledge that claims 23, 26, 29, 31, 33, 35, 41, 42, and 44 are withdrawn. Claims 30, 36-40 and 43 have been cancelled.

Double Patenting Rejection

3-4. Claims 1-22, 24, 25, 27, 28, 30, 32, 34, 36-40, 43 and 45-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-14 of copending application no. 11/127,438. Applicants respectfully request that the

Examiner hold this provisional rejection in abeyance until allowable subject matter is identified in the instant application. Once allowable subject matter has been identified, Applicants will evaluate the filing of a terminal disclaimer or providing arguments in view of the claims pending at that time.

Claim Rejections under 35 U.S.C. § 112

5. Claim 21 was rejected under 35 U.S.C. § 112 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

MPEP 2173.05(b) states:

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Seattle Box Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

The term "substantially reducing" as used in claim 21 is clearly used in the specification to describe the effect of intravenous administration of anti-C5 antibody, but not aerosol administration (see page 23, lines 1-11, page 24, lines 6-14, and Figure 7). Specifically, Figure 7 shows that in a subject in which anti-C5 antibody BB5.1 was administered via aerosol the systemic complement activity was approximately 93% of the control. This is about a 7% reduction which is not a substantial reduction when compared to an intravenous administration which led to an almost 80% reduction of systemic complement activity (see page 25, lines 7-17). One of ordinary skill in the art would understand what is claimed by reference to the above general guidelines stated in the specification. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102

6. Claim 24 is rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Fitch et al. (Circulation (1999) 100:2499-2506). Applicants respectfully traverse this rejection.

Fitch et al. allegedly teach that coronary bypass surgery (CBP) elicits a systemic inflammatory response and a method of administering a humanized single chain monoclonal antibody directed to a human complement component C5 to subjects undergoing CBP. The Examiner alleges that Fitch et al. teach each and every element of the claimed invention, and thus anticipate the claimed invention. Applicants respectfully disagree with this assessment of the teachings of the cited reference. Nevertheless, solely to expedite prosecution, claim 24 has been amended to include the limitations "in the lungs" and "during an asthma attack."

The standard for anticipating a claimed invention is clearly outlined in MPEP 2131, and this standard is further supported by the courts. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1978). "The identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Fitch et al. fail to teach or suggest each and every limitation of the claimed invention. Accordingly, Fitch et al. fail to satisfy the criteria necessary to anticipate the claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103

7. Claims 1-10, 18, 22, 24, 25, 27, 28, 32, and 34 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032). The Examiner

states that Drouin teaches that C5a receptors are increased on bronchial epithelial and smooth muscle cells in sepsis and in asthma and that septic primates and rats that are treated with anti-C5a antibodies have reduced pulmonary edema and lung injury. The Examiner argues that it would have been obvious to a person of ordinary skill in the art to treat subjects with asthma using an antibody that inhibits C5 or C5a based on the teachings of Drouin. Applicants respectfully traverse.

The Examiner argues that the Abstract states that C5aR is relevant to asthma, but in fact, it states that bronchial epithelial and smooth muscle cells participate in sepsis and asthma. Drouin states that C5aR expression is increased in lungs when an LPS model of endotoxemia was used (see final paragraph on page 2028 continuing onto page 2029). However, by contrast, when an OVA model of asthma was used, C5aR expression did not increase (see first full paragraph on page 2029). The data on pages 2028-2029 show C3aR may be relevant for both sepsis and asthma but C5aR appears to be relevant only for sepsis, not asthma. C5aR expression in OVA-challenged lungs did not change on bronchial and alveolar epithelial cells and no statement was made as to whether C5aR changed expression on the smooth muscle cells in this model. This lack of evidence of a change in C5aR expression in lung cells in the asthma model actually teaches away from the instant claims.

The Examiner also states that "Drouin teaches that septic primates and rats that are treated with anti-C5a antibodies have reduced pulmonary edema and lung injury" pointing to page 2031, first column. This refers only to sepsis and thus the endotoxemia model. One of ordinary skill in the art would not find this relevant to the asthma model.

Thus, Drouin does not teach or suggest all elements of claims 1-10, 18, 22, 24, 25, 27, 28, 32, and 34, and it would not have been obvious to one of skill in the art how to make up for these deficiencies, especially since Drouin teaches away from the instant claims. Accordingly, the claims are non-obvious over the cited prior art, and reconsideration and withdrawal of this rejection are respectfully requested.

8. Claims 11-13, 15 and 16 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032) and further in view of Fitch et al. The Examiner states that Drouin does not teach the treatment of human subjects and the h5G1.1 antibody, but that Fitch et al. does. The Examiner argues that is would have been obvious to a person of ordinary skill in the art to use the h5G1.1 antibody to treat airway inflammation in a human target, such as one with asthma. Applicants respectfully traverse.

Drouin and Fitch have been discussed supra. Neither reference teaches that C5aR is relevant to asthma. Thus, Drouin does not teach or suggest all elements of claims 11-13, 15 and 16, and Fitch et al. does not make up for these deficiencies. Accordingly, the claims are non-obvious over the cited prior art, and reconsideration and withdrawal of this rejection are respectfully requested.

9. Claims 17 and 45-48 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032) and further in view of US Patent 4,228,795 ('795 patent) to Babington. The Examiner states that Drouin does not teach a disperser, but that the '795 patent teaches a nebulizer. The Examiner argues that is would have been obvious to a person of ordinary skill in the art to use the nebulizer taught by the '795 patent to administer the anti-C5a antibodies taught by Drouin. Applicants respectfully traverse.

Drouin has been discussed supra, and the '795 patent teaches a nebulizer. Neither reference teaches that C5aR is relevant to asthma. Thus, Drouin does not teach or suggest all elements of claims 11-13, 15 and 16, and the '795 patent does not make up for these deficiencies. Accordingly, the claims are non-obvious over the cited prior art, and reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Please charge any fees or credit any overpayments to our Deposit Account No. 18-1945 from which the undersigned is authorized to draw, under order no. ALXN-P01-102 from which the undersigned is authorized to draw.

Dated: June 13, 2007

Respectfully submitted, (Signed on behalf of A. Varma)

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